UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	MDL Docket No. 2738
This Document Relates To All Cases	

DEFENDANTS JOHNSON & JOHNSON AND JOHNSON & JOHNSON CONSUMER INC.'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE PLAINTIFFS' EXPERTS' OPINIONS REGARDING ALLEGED HEAVY METALS AND FRAGRANCES IN JOHNSON'S BABY POWDER AND SHOWER TO SHOWER

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INTRODUCTION

Plaintiffs' experts have floated speculative theories that there are heavy metals, fragrances and fibrous talc present in Johnson's Baby Powder and Shower to Shower (the "Products") that are separately carcinogenic from the talc itself. These opinions are inadmissible under Rule 702 and *Daubert* for a number of reasons.[1]

First, there is no scientific support for the theory that exposure to any of the heavy metals that plaintiffs' experts contend are present in talcum powder is capable of causing ovarian cancer.[2] Indeed, ***not a single peer-reviewed published article has ever linked these substances to ovarian cancer.*** And even though plaintiffs' experts do not deny the fundamental tenet of toxicology – i.e., that dose

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[1] This motion addresses opinions related to heavy metals, fibrous talc and fragrances that are proffered by the following experts: Arch Carson, Daniel Clarke-Pearson, Robert Cook, Michael Crowley, Sarah Kane, David Kessler, Mark Krekeler, Shawn Levy, William Longo, Anne McTiernan, Patricia Moorman, Laura Plunkett, Mark Rigler, Jack Siemiatycki, Sonal Singh, Ellen Blair Smith, Rebecca Smith-Bindman, Judith Wolf and Judith Zelikoff. Most of these experts lack the basic credentials to offer testimony in this area, but this brief addresses their methodologies rather than their qualifications.

[2] Notably, prior epidemiological studies involving perineal application of talcum powder necessarily take account of the various metal, fragrance and fibrous talc constituents alleged to be in the Products by plaintiffs' experts, at least to the extent those studies examined the Products. And as set forth in defendants' General Causation brief, the body of epidemiological data does not support causation because, inter alia, there is only a weak association in some of the literature, the association is inconsistent, and there is no credible evidence of dose response.

is critical to assessing the toxicity of a substance – not a single one of plaintiffs' experts identified the level of exposure to heavy metals that would be necessary to cause any harm. Moreover, plaintiffs' experts ignore the specific chemical forms of the heavy metals supposedly found in talc, further rendering their opinions unscientific and unreliable.[3]

Second, plaintiffs' fragrances theory is similarly unscientific and inadmissible. Michael Crowley, their primary expert on the alleged association between fragrances and ovarian cancer, consistently misunderstood or misapplied

[3] The portions of plaintiffs' experts' reports containing opinions regarding heavy metals that defendants seek to exclude are: Expert Report of Arch Carson, M.D., Ph.D. ("Carson Rep.") at 5-8, Nov. 16, 2018 (attached as Ex. C9 to Certification of Julie Tersigni, Esq. ("Tersigni Cert.")); Expert Report of Daniel L. Clarke-Pearson, M.D. ("Clarke-Pearson Rep.") at 6, 9, Nov. 16, 2018 (attached as Ex. C14 to Tersigni Cert.); Expert Report of Sarah E. Kane, M.D. ("Kane Rep.") at 5, 29, 36, Nov. 15, 2018 (attached as Ex. C38 to Tersigni Cert.); Expert Report of Shawn Levy, Ph.D. ("Levy Rep.") at 15-17, Nov. 16, 2018 (attached as Ex. C39 to Tersigni Cert.); Expert Report of Patricia G. Moorman, M.S.P.H., Ph.D. ("Moorman Rep.") at 35, Nov. 16, 2018 (attached as Ex. C35 to Tersigni Cert.); Expert Report of Laura M. Plunkett, Ph.D., D.A.B.T. ("Plunkett Rep.") at 24, 77-78, Nov. 16, 2018 (attached as Ex. C28 to Tersigni Cert.); Expert Report of Jack Siemiatycki, M.S.C., Ph.D. ("Siemiatycki Rep.") at 65-66, Nov. 16, 2018 (attached as Ex. C21 to Tersigni Cert.); Expert Report of Sonal Singh, M.D., M.P.H. ("Singh Rep.") at 16, 60, Nov. 16, 2018 (attached as Ex. C40 to Tersigni Cert.); Expert Report of Ellen Blair Smith, M.D. ("Smith Rep.") at 19, 21-22, Nov. 16, 2018 (attached as Ex. C16 to Tersigni Cert.); Expert Report of Rebecca Smith-Bindman, M.D. ("Smith-Bindman Rep.") at 5, 14, 16, 40, Nov. 15, 2018 (attached as Ex. C36 to Tersigni Cert.); Expert Report of Judith Wolf, M.D. ("Wolf Rep.") at 9-10, 16, Nov. 16, 2018 (attached as Ex. C23 to Tersigni Cert.); Expert Report of Judith Zelikoff, Ph.D. ("Zelikoff Rep.") at 8-12, 27, Nov. 16, 2018 (attached as Ex. C24 to Tersigni Cert.).

the regulatory opinions and other source materials on which he purports to have relied. Furthermore, none of plaintiffs' experts is able to point to any scientific literature even suggesting a link between exposure to fragrances and ovarian cancer. And plaintiffs have zero evidence that the amount of fragrances added to talcum powder – which, in total, consists of less than one percent of the overall product – is capable of contributing to the supposed carcinogenicity of talc.[4]

Third, many of plaintiffs' experts, to a greater or lesser degree, opine that so-called fibrous talc can contribute to ovarian cancer. But the literature on which they rely discusses an entirely different, though similarly named, substance from the one purportedly found in the Products. In short, to the extent the literature suggests that fibrous talc can cause cancer, it refers to talc that is intergrown with asbestos, or, at the very least, that crystallized in an asbestiform habit. Although plaintiffs' experts Drs. Longo and Rigler purport to have found ***elongated*** talc particles in the Products, they offer no evidence that those particles crystallized in an asbestiform habit. No scientific evidence has even suggested a link between this type of fibrous talc and ovarian cancer; and to the extent fibrous talc is contained in the Products, any ostensible risk posed by fibrous talc is already

[4] The portions of plaintiffs' experts' reports containing opinions regarding fragrances that defendants seek to exclude are: Carson Rep. at 6-8; Clarke-Pearson Rep. at 6, 9; Kane Rep. at 29, 36; Levy Rep. at 15-17; Moorman Rep. at 35; Plunkett Rep. at 23, 77-78; Singh Rep. at 60; Smith Rep. at 19, 21-22; Smith-Bindman Rep. at 14, 16; Wolf Rep. at 10, 17; Zelikoff Rep. at 12, 27.

captured by existing epidemiological literature investigating perineal talc use and ovarian cancer.[5]

For all of these reasons, discussed further below, the Court should exclude these opinions under Rule 702 and *Daubert*.

BACKGROUND

A. Heavy Metals

1. Talc Mining And Processing

Talc is a mineral derived from metamorphic deposits.[6] Each talc mine "has its own character."[7] Talc deposits may consist of pure talc or contain varying amounts of accessory minerals.[8] Moreover, different accessory minerals may be

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[5] The portions of plaintiffs' experts' reports containing opinions regarding fibrous talc that defendants seek to exclude are: Carson Rep. at 5, 7; Clarke-Pearson Rep. at 5-6, 9; Am. Expert Report of Robert B. Cook, Ph.D. ("Am. Cook Rep.") at 2, 4, 9, 10, 21-28, 42, Jan. 22, 2019 (attached as Ex. C2 to Tersigni Cert.); Kane Rep. at 5, 29; Expert Report of David A. Kessler, M.D. ("Kessler Rep.") at 19, 21, Nov. 16, 2018 (attached as Ex. C15 to Tersigni Cert.); Expert Report of Mark Krekeler, Ph.D. ("Krekeler Rep.") at 14-30, 45 (attached as Ex. C31 to Tersigni Cert.); Expert Report of William E. Longo, Ph.D. & Mark W. Rigler, Ph.D. ("Longo & Rigler Rep.") at 15, Nov. 14, 2018 (attached as Ex. C41 to Tersigni Cert.); Expert Report of Anne McTiernan, M.D. ("McTiernan Rep.") at 8-9, 56, Nov. 16, 2018 (attached as Ex. C7 to Tersigni Cert.); Moorman Rep. at 35, 38-39; Plunkett Rep. at 17-21, 25-26, 46, 53, 66, 67-69, 77-78; Siemiatycki Rep. at 29, 65-66; Singh Rep. at 14-16; Smith Rep. at 18-19, 21-22; Smith-Bindman Rep. at 5, 14-15, 40; Wolf Rep. at 9, 15; Zelikoff Rep. at 4, 8.

[6] (Krekeler Rep. at 2.)

[7] (*Id.* at 5.)

[8] (*Id.*)

found in talc deposits depending on the geographic location, age and temperature of the talc mine and other details about the conditions of formation.[9] Even talc ore within close proximity may have "different mineral profiles."[10]

Many talc ores consist of only 50 to 70 percent pure talc.[11] Because finished talc products generally have talc content between 95 and 99 percent, non-talc material must be removed post-mining through the beneficiation process.[12] Beneficiation may consist of "a variety of techniques that includes selective mining, hand sorting and milling by roller mills, hammer mills, ball mills, fluid energy mills and jet mills and are classified and separated from other minerals by froth flotation or magnetic separation."[13]

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9 (Dep. of Robert Cook Ph.D. ("Cook Dep.") 131:18-132:7, Jan. 30, 2019 (attached as Ex. B43 to Tersigni Cert.).)

10 (Dep. of Mark Krekeler ("Krekeler Dep.") 169:2-6, Jan. 25, 2019 (attached as Ex. B34 to Tersigni Cert.).)

11 (Am. Cook Rep. at 9.)

12 (*Id.*)

13 Int'l Agency for Research on Cancer, World Health Org., 93 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Carbon Black, Titanium Dioxide, and Talc* 286 (2010) ("IARC 2010 Monograph") (attached as Ex. A72 to Tersigni Cert.). (*See also* Krekeler Dep. 154:22-155:1, 155:7-156:18, 158:22-159:1).

Several of plaintiffs' experts claim that the Products contain various heavy metals that contribute to the Products' purported carcinogenicity.[14] In forming their opinions that the Products contain heavy metals, these experts rely primarily on documents provided by plaintiffs' counsel.[15] Notably, Dr. Krekeler conceded that the selected documents provided by plaintiffs' counsel may have contained testing results that were taken ***not*** from the talc ore used to create the Products, but instead, from the surrounding rock to demarcate the areas of ore that was ***not*** suitable for mining.[16] Dr. Krekeler also agreed that the levels of heavy metals found in ore samples may not be indicative of the levels of those metals in the Products.[17] And several plaintiffs' experts conceded that they had no way of knowing how much, if any, metal ultimately ended up in the Products.[18]

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14 (*See* Krekeler Rep. at 7-8; Am. Cook Rep. at 36; Zelikoff Rep. at 11; Plunkett Rep. ¶ 36; Carson Rep. at 5-6.)

15 (*See, e.g.*, Krekeler Dep. 30:7-9; Cook Dep. 34:16-20; Zelikoff Dep. 292:1-6.)

16 (Krekeler Dep. 147:22-25, 150:11-17, 152:22-153:9.)

17 (*Id.* 276:6-14.)

18 (*Id.* 277:24-278:5; Dep. of Arch I. Carson, M.D., Ph.D. ("Carson Dep.") 176:5-10, 177:20-24, Jan. 19, 2019 (attached as Ex. B5 to Tersigni Cert.); Dep. of Judith Zelikoff, Ph.D. ("Zelikoff Dep.") 271:18-272:2, Jan. 21, 2019 (attached as Ex. B31 to Tersigni Cert.).)

2. There Is No Scientific Link Between Heavy Metal Exposure And Ovarian Cancer.

Plaintiffs also proffer the opinions of three toxicologists – Drs. Zelikoff, Plunkett and Carson – along with those of a few epidemiologists and gynecologic oncologists who lack independent knowledge or expertise in this area, to support their claim that the purported heavy metals found in the Products cause or contribute to the carcinogenicity of those products.

Dr. Zelikoff was asked "to review the scientific literature and assess whether there is a biologically plausible explanation for the increased risk of ovarian cancer with the perineal use of talcum powder products."[19] Among other opinions, Dr. Zelikoff asserts that the "presence of . . . inflammatory agents [like heavy metals] provides additional biologic evidence explaining the causal relationship between genital talc use and ovarian cancer."[20] But Dr. Zelikoff conceded at her deposition that she is not aware of any studies that suggest that exposure to heavy metals can cause inflammation in the ovaries.[21] And none of the studies Dr. Zelikoff cites in her report suggests that exposure to heavy metals increases the risk for ovarian cancer.[22]

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19 (Zelikoff Rep. at 2.)

20 (*Id.* at 12.)

21 (Zelikoff Dep. 291:14-24, 313:21-314:3.)

22 (*Id.* 282:2-8.)

Dr. Carson similarly claims that heavy metals purportedly found in talcum powder cause ovarian cancer. According to Dr. Carson, the heavy metal ions purportedly present in talc "leach out of the talcum powder slowly over time, resulting in continuous, low-level exposure of the surrounding tissues to carcinogenic metals."[23] Dr. Carson conceded that chromium, cobalt and nickel are "natural elements" that are "present in food, drinking water, bottled water [and] vitamins," and that he had no evidence that any of these metals was found in higher levels in the blood or tissue of talc users as compared to non-users.[24]

Likewise, Dr. Plunkett asserts that the "known toxic effects of . . . components of talcum powder products" support her theory that "genital exposure to talcum powder products increases the risk of ovarian cancer in women."[25] But in her report, she does not cite to a single study that shows that any of the heavy metals purportedly found in talc increases the risk of ovarian cancer.[26]

In addition to these toxicologists, a number of plaintiffs' epidemiologists and gynecologic oncologists also opine that the heavy metals in talcum powder

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23 (Carson Rep. at 5.)

24 (Carson Dep. 169:24-170:16.)

25 (Plunkett Rep. ¶ 117.)

26 (Dep. of Laura Plunkett, Ph.D., D.A.B.T. ("Plunkett Dep.") 274:17-275:8, Dec. 19, 2018 (attached as Ex. B33 to Tersigni Cert.) ("I mean, no, I haven't done a specific assessment of ovarian cancer risk with each of those metals individually.").)

contribute to or cause ovarian cancer.[27] None of plaintiffs' epidemiologists and gynecologic oncologists is able to cite any studies linking heavy metal exposure to ovarian cancer either.[28]

3. Plaintiffs' Experts Fail To Identify The Alleged Dose Of Heavy Metals To Which Women Are Exposed From The Products – Or What Dose They Believe To Be Dangerous.

Plaintiffs' experts acknowledge the most fundamental tenet of toxicology: i.e., that the dose, or the amount of exposure to a substance, is critical to determining whether it poses a risk to human health.[29] Dr. Zelikoff testified that the "dose as well as frequency, duration, time of exposure" all "contribute to the toxicity of an agent."[30]

Yet, not a single one of plaintiffs' experts addresses the threshold at which exposure to chromium, cobalt or nickel induces carcinogenesis or has any effect on

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[27] (*See* Clarke-Pearson Rep. at 9; Kane Rep. at 5-6; McTiernan Rep. at 58; Siemiatycki Rep. at 66; Singh Rep. at 60; Smith Rep. at 19; Smith-Bindman Rep. at 5, 16; Wolf Rep. at 10.)

[28] Plaintiffs' experts' willingness to adopt a kitchen-sink approach by adding in various speculative causal theories is a tacit acknowledgment that their core causation theory that talc causes some unspecified subtype of ovarian cancer lacks sufficient scientific support. And the fact that they are willing to endorse the heavy-metal and fragrance theories without even citing a single study evinces an alarming disregard for the scientific method that highlights the unreliability of their broader opinions.

[29] (*See, e.g.*, Carson Dep. 310:23-311:5.)

[30] (Zelikoff Dep. 262:6-15; *see also* Plunkett Dep. 234:20-23 (agreeing that dose is important to determine risk).)

human health. Nor did any of plaintiffs' experts make any effort to analyze the amount of exposure to heavy metals a woman would incur by using the Products.[31] This omission is especially glaring given that, as Dr. Carson acknowledges, only "very small quantities" of heavy metals are present "in some [talc] deposits."[32]

In an effort to bridge this gap, some of plaintiffs' experts (including Drs. Carson and Zelikoff) opined, for the first time at their depositions, that any exposure to heavy metals could cause ovarian cancer.[33] But once again, none of plaintiffs' experts was able to point to any scientific studies or other evidence corroborating their opinions:

> Q. . . . . Is it your opinion that one particle of cobalt, either inhaled or applied to the perineum, will induce inflammation in the ovaries?
>
> A. Again, it's my opinion that it – it could. It has the biological plausibility to, because inflammation, although not as toxic in many ways as it's classified as a 2B – 2B by IARC is – has the potential – does cause inflammation, and that inflammation can leave the site of the target site.
>
> Q. What authority do you have for that opinion?

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[31] (*See, e.g.*, Plunkett Dep. 263:15-264:3 (explaining that she has "not done a – a calculation of a potential dose with perineal application for any of the heavy metals"); Carson Dep. 171:1-21 (admitting that he does not know the amount of exposure to heavy metals that results from talc use and stating that it would be "useful to factor in the amount if the amount is known").)

[32] (Carson Dep. 169:10-23 (further explaining that he could not say how much of those metals, if any, reach a woman's ovaries when she uses talc).)

[33] (*See, e.g., id.* 171:6-20; Zelikoff Dep. 319:23-321:1, 321:21-322:21.)

A. My professional opinion.[34]

B. <u>The Fragrances Added To The Products</u>

Fragrances used in consumer products in the United States are regulated in several different ways.

A number of federal laws govern the information a manufacturer is required to provide on the label about fragrance ingredients. The Federal Food, Drug, and Cosmetic Act requires manufacturers to list the word "fragrance" or another similar term when fragrance ingredients are added to a product.[35] The Consumer Product Safety Act and the Federal Hazardous Substances Act likewise require the manufacturer to provide certain information about fragrance ingredients added to a product.[36] And the Toxic Substances Control Act "authorizes the EPA to secure information on all new and existing chemicals (or mixtures) sold in interstate commerce."[37]

The International Fragrance Association ("IFRA") is the official self-regulatory representative body of the fragrance industry worldwide.[38] As plaintiffs' expert Dr. Crowley explains, "IFRA's main purpose is to ensure the

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34 (Zelikoff Dep. 319:24-321:1.)

35 (Expert Report of Michael M. Crowley, Ph.D. ("Crowley Rep.") at 18, Nov. 12, 2018 (attached as Ex. C34 to Tersigni Cert.) (citing 21 C.F.R. § 701.3).)

36 (*Id.*)

37 (*Id.*)

38 (*Id.* at 13.)

safety of fragrance materials through a dedicated science program and . . . usage standards for fragrance materials, limiting or prohibiting the use of ingredients based on the findings of the Research Institute of Fragrance Materials (RIFM)."[39] To set usage standards, IFRA relies on RIFM's independent panels of experts in the fields of dermatology, toxicology, pathology and environmental sciences.[40] The role of the experts on the panel is to evaluate a particular fragrance ingredient to determine whether the data support the current use level.[41] If the evaluation does not support the current use of the chemical, the panel instructs IFRA to issue a Standard either restricting or banning the material.[42]

Johnson's Baby Powder contains a mixture of 141 fragrance ingredients.[43] By weight, fragrances constitute just 0.22 percent of Johnson's Baby Powder, with the remaining 99.78 percent of the product consisting of talc.[44] Shower to Shower contains a fragrance mixture comprised of 53 fragrances.[45] By weight, fragrances constitute 0.55 percent of Shower to Shower, with the remaining 99.45 percent of

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39 (*Id.*)

40 (IFRA Standards (Ex. 18 to the Dep. of Michael Crowley, Ph.D., Jan. 4, 2019) (attached as Ex. B38 to Tersigni Cert.).)

41 (*Id.*)

42 (*Id.*)

43 (Crowley Rep. at. 11.)

44 (*See* JNJTALC000891091 (attached as Ex. D6 to Tersigni Cert.).)

45 (Crowley Rep. at 11.)

the product consisting of talc, corn starch, baking soda and calcium hydroxyapatite.[46]

Plaintiffs suggest that these added fragrances contribute to the alleged carcinogenicity of the Products. In support of this claim, plaintiffs primarily offer the opinions of Michael Crowley. Dr. Crowley is the president of Theridian Technologies, LLC, a pharmaceutical development consulting firm that he established in March 2009.[47] Although he has developed pharmaceutical products and published a "significant amount of articles concerning pharmaceutical formulation techniques,"[48] Dr. Crowley has never written on the topic of fragrance chemicals.[49]

Dr. Crowley admitted at his deposition that there are no human studies linking ***any*** of the fragrances in the Products to ovarian cancer in humans.[50] He also conceded that the animal data on which he relies do not relate to ovarian cancer or other gynecological cancers.[51] And he acknowledged that, even when a

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46 (*See* JNJTALC001021615 (attached as Ex. D7 to Tersigni Cert.).)

47 (Crowley Rep. at 14.)

48 (*Id.* at 15.)

49 (Dep. of Michael Crowley, Ph.D. ("Crowley Dep.") 65:5-8, Jan. 4, 2019 (attached as Ex. B37 to Tersigni Cert.).)

50 (*Id.* 114:22-115:6; *see also id.* 185:4-8, 195:21-196:18.)

51 (*See, e.g., id.* 262:1-8 (agreeing that the only potential association found between d-Limonene and cancer in animal studies is to renal tubular tumors); *see*

(cont'd)

substance may be capable of causing cancer in animals, it may not in humans.[52] Likewise, he agreed that a substance may increase the risk of some types of cancer without having any impact on other types of cancer.[53]

Moreover, although Dr. Crowley agrees that "poisons" generally have a "dose-and-exposure relationship,"[54] he made no effort to determine whether a consumer would actually be exposed to harmful levels of fragrances by using the Products.[55] Dr. Crowley blamed his failure to conduct a dose-response assessment on his belief that he lacked information sufficient to determine the amount of fragrance ingredients added to the Products or the concentration of any particular fragrance ingredient in a bottle.[56] But a number of documents produced to

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also, e.g., *id.* 265:2-12 (only potential association between coumarin and cancer is "alveolar/bronchiolar tumors, adenomas, and carcinomas in both males and females, hepatocellular adenomas in females, and . . . squamous cell papillomas and carcinomas of the stomach"); *id.* 277:5-16 (benzophenone exposure only associated with increased incidence of hepatocellular cancer, histiocystic sarcoma, leukemia and renal tubal adenoma); *id.* 296:1-6 (no animal study associating musk ketone with ovarian cancer).)

52 (*Id*. 212:22-213:2.)

53 (*Id.* 212:14-20.)

54 (*Id.* 129:5-6.)

55 (*Id.* 107:21-108:5.)

56 (*Id.* 136:8-137:13, 168:16-22, 201:7-202:6, 225:14-226:3, 232:23-233:13, 252:19-253:12, 286:10-287:3, 302:9-303:7, 312:8-22.)

plaintiffs contained information about the maximum concentration of fragrance ingredients in the Products.[57]

Perhaps recognizing that his failure to assess dose or exposure deprived his opinions of scientific footing, Dr. Crowley suggested for the first time at his deposition that some of the fragrances used in the Products are "genotoxic."[58] According to Dr. Crowley, "[y]ou don't need to do a dose response relationship for a genotoxic material, because genotoxins you need one molecule for there to be an increased risk, one."[59]

C. Fibrous Talc

Many of plaintiffs' experts contend, in very terse and virtually identical statements, that JJCI talcum powder can contribute to the risk of cancer in part

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[57] (*See, e.g.*, JNJTALC000891091-104 (formula declaration report setting forth total amount of fragrance by weight); JNJTALC000149667-68 (attached as Ex. D4 to Tersigni Cert.) (same); Letter from Chris Tisi to Susan Sharko, Aug. 30, 2018 (attached as Ex. H1 to Tersigni Cert.) (requesting that defendants "produce all formulas including any fragrance chemicals, additives, sterilization agents, reagents, or other additives for JBP and STS"); Exs. 1-3 to Response Email from Richard T. Bernardo to Chris Tisi, Oct. 16, 2018 ("Attorneys' Eyes Only Exs. 1-3") (attached collectively as Ex. H2 to Tersigni Cert.) (setting forth the minimum and maximum amounts of each fragrance ingredient added to Johnson's Baby Powder and Shower to Shower).)

[58] (Crowley Dep. 124:14-16.)

[59] (*Id.* 124:16-20; *see also, e.g., id.* 125:20-23 ("As I just indicated, genotoxic materials do not – are not thresholded. They don't have a threshold. One molecule is enough to cause an increased risk."); *id.* 131:22-24 ("genotoxic materials do not live under a dose response relationship"); *id.* 357:18-20 ("the question about dose is immaterial with genotoxic materials").)

because it includes fibrous talc. It became clear at depositions, however, that these experts do not understand what fibrous talc is.[60] Instead, one after another, the experts rested their opinions solely on Drs. Longo and Rigler's findings and the conclusions of the International Agency for Research on Cancer ("IARC"). But the IARC statement on which the experts rely does not refer to the sort of fibrous talc purportedly found by Drs. Longo and Rigler: i.e., any particle with "a 5:1 aspect ratio or greater, at least 0.5 µm in length and [having] substantially parallel sides."[61] It only refers to talc intergrown with or contaminated by true asbestos, or, at the very least, talc that grows in an asbestiform habit – i.e., talc that naturally grows into or forms as a "fibrous aggregate of long, thin and flexible crystals that readily separate into smaller crystals of a similar length to width aspect ratio."[62] In fact, IARC expressly states that "talc products that contain elongated mineral fragments that are not asbestiform" are not included in its pronouncement.[63] As

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60 (*See, e.g.*, Dep. of Ellen Blair Smith, M.D. ("Smith Dep.") 141:13-20, Jan. 9, 2019 (attached as Ex. B11 to Tersigni Cert.) (deferring to others on the difference between fibrous talc and talc containing asbestiform fibers); Dep. of Anne McTiernan, M.D., Ph.D. 266:10-13, Jan. 28, 2019 (attached as Ex. B2 to Tersigni Cert.) (admitting that she could not distinguish between fibrous talc and fibrous minerals).)

61 (Longo & Rigler Rep. at 11.)

62 (Krekeler Rep. at 4.)

63 Int'l Agency for Research on Cancer, World Health Org., 100C *Monographs on the Evaluation of Carcinogenic Risks to Humans: Arsenic, Metals, Fibres, and*

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defendants' expert Dr. Mossman explained in her report, "Fibrous talcs not containing asbestos fibers have not been classified as human carcinogens[64] and are structurally and chemically different from asbestos or asbestiform fibers."[65]

ARGUMENT

Plaintiffs' experts' opinions that the purported (1) heavy metals, (2) fragrances and (3) fibrous talc in the Products cause ovarian cancer are unreliable and inadmissible because they have not cited any evidence indicating that any of these substances has been associated with ovarian cancer in any circumstances, much less any evidence of the degree of exposure necessary to cause injury or that JJCI's talcum powder could produce such exposures.[66]

I. PLAINTIFFS' EXPERTS' OPINIONS THAT PURPORTED HEAVY METALS FOUND IN TALC CAN CAUSE OVARIAN CANCER ARE UNRELIABLE.

Plaintiffs' experts' opinions that heavy metals purportedly found in the Products can cause ovarian cancer must be excluded as unreliable for multiple

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Dust 230 (2012) ("IARC 2012 Monograph") (attached as Ex. A70 to Tersigni Cert.).

64 (IARC 2010 Monograph at 412.)

65 (Mossman Rep. at 23.)

66 Dr. Siemiatycki's choice of words in describing these theories in his report aptly underscores their speculative and hypothetical nature. Specifically, he states: "The evidence that commercial cosmetic talcum powder products have been shown to contain asbestos, fibrous talc, and heavy metals . . . provides a reasonable basis ***for hypothesizing*** that these chemicals ***may contribute*** to the carcinogenicity of the talcum powder products." (Siemiatycki Rep. at 65-66 (emphases added).)

reasons. ***First***, there is no scientific support for the notion that exposure to these metals causes ovarian cancer; indeed, none of plaintiffs' experts was able to point to a single study suggesting such an association. ***Second***, even if there were some association between exposure to these metals and ovarian cancer, none of plaintiffs' experts can identify the amount of exposure to heavy metals that would render them toxic. Plaintiffs' experts offer no opinions on the amount of heavy metals to which a talc user would be exposed and do not even know the concentration of heavy metals found in the Products. ***Third***, several of plaintiffs' experts ignore the specific chemical forms of the heavy metals supposedly found in talc, further rendering their opinions unreliable.

A. There Are No Scientific Studies Linking Heavy Metal Exposure To Ovarian Cancer.

Plaintiffs' experts' heavy metal opinions should first be excluded because they cannot identify a single scientific study linking exposure to these metals with ovarian cancer.

Courts around the country have precluded experts from testifying as to causation where there is no scientific evidence that associates exposure to the alleged carcinogen and the "specific disease from which [plaintiff] suffers." *Sutera v. Perrier Grp. of Am. Inc.*, 986 F. Supp. 655, 662 (D. Mass. 1997); *see also, e.g., Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145-46 (1997) (district court properly excluded expert opinion that plaintiff's exposure to PCBs contributed to

his cancer where the studies underlying the expert's opinion "did not suggest a link between the increase in lung cancer deaths and the exposure to PCBs"); *Burleson v. Tex. Dep't of Criminal Justice*, 393 F.3d 577, 586 (5th Cir. 2004) (expert testimony unreliable where "there [we]re no epidemiological studies supporting a correlation between the suggested causative agent and the type of cancer experienced by the plaintiff"); *Nat'l Bank of Commerce v. Associated Milk Producers, Inc.*, 22 F. Supp. 2d 942, 983 (E.D. Ark. 1998) (excluding expert testimony on causation where experts could not point to any "scientific studies or medical literature that show[ed] any correlation between exposure to [the purported carcinogen] and laryngeal cancer"), *aff'd*, 191 F.3d 858 (8th Cir. 1999); *Wade-Greaux v. Whitehall Labs., Inc.*, 874 F. Supp. 1441, 1453, 1468 (D.V.I. 1994) ("Absent consistent, repeated human epidemiological studies showing a statistically significant increased risk of particular birth defects associated with exposure to a specific agent, the community of teratologists does not conclude that the agent is a human teratogen."), *aff'd*, 46 F.3d 1120 (table), 1994 WL 16973481 (3d Cir. 1994).

For example, in *McCarty v. Arch Wood Protection, Inc.*, No. 11-109-HRW-CJS, 2016 WL 2936435 (E.D. Ky. Feb. 26, 2016), *report and recommendation adopted*, No. 11-109-HRW, 2016 WL 1306067 (E.D. Ky. Mar. 31, 2016), the plaintiff claimed that he had been exposed to toxic levels of chromated copper

arsenate ("CCA") over the course of his 21-year career, which he claimed caused him to develop pulmonary nodular lymphoid hyperplasia ("PNLH"). *Id.* at *1. The plaintiff offered the testimony of two toxicologists who opined that the plaintiff's exposure to arsenic (a component of CCA) could have contributed to his development of PNLH. *Id.* at *7-12. The court excluded the opinions of both experts because neither of them was able to point to a "direct connection in the literature between arsenic exposure and the formation of PNLH" – even though there was some discussion in the literature that the exposure could cause biological effects in other parts of the body. *Id.* at *8; *see also id.* at *11 (noting that, although one study suggested proliferation of the lymph nodes near the ear from CCA exposure, there were no studies showing lung involvement).

Allen v. Pennsylvania Engineering Corp., 102 F.3d 194 (5th Cir. 1996), is also instructive. In that case, the decedent – who worked in hospital maintenance for more than 20 years – was tasked with replacing cylinders containing ethylene oxide ("EtO"), a chemical used to sterilize medical devices, during the course of his employment. *Id.* at 195. After he died of glioblastoma multiforme, a type of brain cancer, his widow and son filed suit, alleging that the decedent's exposure to EtO caused his brain cancer. *Id.* The district court excluded the opinions of plaintiffs' three causation experts because, among other things, their opinions lacked "sufficient scientific grounding," and the Fifth Circuit affirmed. *Id.* In its

affirmance, the court of appeals explained that, "although occupational exposure to EtO has been studied for many years, not a single scientific study has revealed a link between human brain cancer and EtO exposure." *Id.* at 197. And while the plaintiffs' experts had pointed to evidence "that suggests a connection between EtO exposure and human lymphatic and hematopoetic cancers," such evidence was not "probative on the causation of brain cancer." *Id.*

The same is true here: none of plaintiffs' experts is able to point to a single study connecting exposure to any heavy metal allegedly at issue with any of the subtypes of ovarian cancer. For example, Dr. Zelikoff discusses the carcinogenicity of nickel, chromium and cobalt in her report.[67] With respect to each metal, Dr. Zelikoff lists a litany of "adverse effects on human health" resulting from exposure.[68] But Dr. Zelikoff conceded that she did not find ***any*** studies that discussed the potential of ***any*** of these heavy metals to cause ovarian cancer:

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67 (Zelikoff Rep. at 8-10.)

68 (*Id.* at 8-9 (noting that nickel exposure may lead to dermatitis, lung fibrosis, cardiovascular and kidney diseases, cancer of the respiratory tract, nasal and sinusoidal cancers and cancers of the lungs and larynx); *id.* at 9-10 (stating that exposure to hexavalent chromium can cause cancer, occupational asthma, eye and respiratory irritation, perforated eardrums, kidney and liver damage, pulmonary congestion and edema, abdominal pain, skin irritation and erosion or discoloration of teeth); *id.* at 10 (cobalt can lead to "DNA breakage," "inhibition of DNA repair" and allergic reactions).)

> Q. . . . Did you find any studies reporting on a risk of ovarian cancer with exposure to any of these metals, that being cobalt, chromium, or nickel?
>
> A. I was not looking specifically for that. So, no, I did not find that.[69]

Indeed, Dr. Zelikoff is not aware of ***any*** ex vivo or in vitro studies that examined whether these metals had any effect on human ovarian cells, much less caused ovarian cancer.[70] Plaintiffs' other experts are in accord: not a single one found a study discussing any purported association between heavy metals and ovarian cancer.[71]

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[69] (Zelikoff Dep. 285:22-286:4; *see also id.* 281:1-15 (clarifying that she did "not talk about ovarian cancer in particular relation to these three metals" in her report); *id.* 282:2-8 (conceding that she does not cite any study that looked at the ovarian carcinogenicity potential of these metals).)

[70] (*Id.* 294:14-295:4.)

[71] (Dep. of Sonal Singh, M.D., M.P.H. 298:24-299:10, Jan. 16, 2019 (attached as Ex. B47 to Tersigni Cert.) (stating that he was "not aware of studies that link [heavy metals] directly to ovarian cancer"); Dep. Daniel L. Clarke-Pearson, M.D. ("Clarke-Pearson Dep.") 290:19-291:10, Feb. 4, 2019 (attached as Ex. B10 to Tersigni Cert.) (stating that he does not "think that anybody's ever studied" whether exposure to heavy metals can cause ovarian cancer); Smith Dep. 376:14-19 (testifying that although IARC has classified some heavy metals as carcinogens, "there's been no association with ovarian cancer made in their report"); Dep. of Judith K. Wolf, M.D. ("Wolf Dep.") 405:4-7, Jan. 7, 2019 (attached as Ex. B30 to Tersigni Cert.) ("I'm not aware that anybody has looked at [nickel, chromium or cobalt] by themselves to cause – to assess the risk of ovarian cancer."); Plunkett Dep. 274:17-275:8 ("I mean, no, I haven't done a specific assessment of ovarian cancer risk with each of those metals individually."); Dep. of Patricia G. Moorman, M.S.P.H., Ph.D. 122:12-19, Jan. 25, 2019 (attached as Ex. B39 to Tersigni Cert.) ("Q. Do you hold the independent opinion that cadmium, chromium, and cobalt cause ovarian cancer? . . . A. . . . I am not aware of papers that have directly

(cont'd)

Lacking any supportive science, some of plaintiffs' experts speculate that the purported presence of heavy metals in cosmetic talc could contribute to talc's supposed carcinogenicity by causing inflammation.[72] But this alternative theory is also unreliable. As a threshold matter, there is no reliable basis for opining that inflammation can cause ovarian cancer at all, for all the reasons set forth in defendants' Biological Plausibility brief, filed separately. As elaborated in that brief, although inflammation allegedly caused by talc has been hypothesized as potentially playing a role in causing ovarian cancer, the available science does not support that hypothesis. Rather, the only reliable scientific evidence suggests that inflammation is an effect, and not a cause, of ovarian cancer.

(cont'd from previous page)
addressed those metals in relation to ovarian cancer risk.") (objection omitted); Dep. of Sarah E. Kane, M.D. ("Kane Dep.") 141:14-23, Jan. 25, 2019 (attached as Ex. B45 to Tersigni Cert.) ("There is not, to my knowledge – looking at what IARC looked at, there's not data right now on those heavy metals and ovarian cancer, but it's – it's a – it's a piece of the puzzle.").)

[72] (*See, e.g.*, Smith-Bindman Rep. at 16 ("Any and all of these heavy metals can cause ovarian cancer through an inflammatory mechanism."); Smith Rep. at 19 ("These heavy metals likely contribute to the carcinogenicity of talcum powder products by the inflammatory mechanism described at length in this report."); Levy Rep. at 16 ("The presence of asbestos, nickel, and chromium, known carcinogens, in talcum powder products provides further support for the conclusion that talcum powder causes chronic inflammation."); Zelikoff Rep. at 12-13 ("Each of these elements individually and together can contribute to an inflammatory response caused by the product. . . . [I]nflammation is a known mediator of ovarian cancer. The presence of these inflammatory agents provides additional biologic evidence explaining the causal relationship between genital use of talc and ovarian cancer.").)

Moreover, and in any event, there is no evidence that any of the alleged metals found in talcum powder can even cause inflammation of the ovaries. As plaintiffs' genetics expert put it, there is no "direct evidence for heavy metal contribution to the inflammation process."[73] Likewise, as Dr. Zelikoff conceded, "there are no studies that demonstrate" that the heavy metals purportedly found in talc cause inflammation in the ovary.[74]

In short, because there is zero scientific evidence supporting the proposition that heavy metal exposure can cause ovarian cancer, plaintiffs' experts' opinions that the supposed heavy metals in talc "contribute" to its alleged "carcinogenicity" amount to sheer, unscientific speculation, and the Court should exclude them under *Daubert*.

B. Plaintiffs' Experts' Methods Are Unreliable Because They Fail To Address Dosage And Exposure Concentration.

Plaintiffs' experts' opinions on the alleged relationship between heavy metal exposure and ovarian cancer are fundamentally flawed for a second, independent reason: plaintiffs' experts wholly ignore dosage and exposure concentration.

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[73] (Dep. of Shawn Levy, Ph.D. 353:15-17, Jan. 11, 2019 (attached as Ex. B46 to Tersigni Cert.).)

[74] (Zelikoff Dep. 291:3-24.) Even if there were evidence for a pro-inflammatory effect of any of the heavy metals allegedly at issue, it would remain to be shown that the Products contained heavy metals in sufficient quantities to produce that inflammatory effect – which, as further detailed in the next section, no plaintiffs' expert has even attempted to show.

It is a "central tenet[] of toxicology" that the "dose makes the poison."[75] As Dr. Zelikoff admitted at her deposition, "dose as well as frequency, duration, time of exposure . . . all . . . contribute to the toxicity of an agent."[76] Indeed, "most materials could be hazardous if too much is consumed or if the exposure is too great."[77] Accordingly, a toxicologist must consider not only the nature of the toxin, but also the amount of exposure or dose, to assess whether a particular agent poses a risk to human health.

Consistent with these bedrock scientific principles, courts have made clear that expert opinions regarding the alleged hazards posed by a particular substance are unreliable, and therefore must be excluded where – as here – the expert is unable to specify the dose that renders the substance toxic or to confirm that the plaintiff was exposed to such a dose. *See, e.g.*, *Burleson*, 393 F.3d at 587

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75 Goldstein & Henifin, Fed. Judicial Ctr., *Reference Guide on Toxicology, in Reference Manual on Scientific Evidence* 633, 636 (3d ed. 2011) ("Toxicology Reference Manual") (attached as Ex. A46 to Tersigni Cert.).

76 (Zelikoff Dep. 262:11-15; *accord* Expert Report of H. Nadia Moore, Ph.D., D.A.B.T., E.R.T. ("Moore Rep.") at 8, Feb. 25, 2019 (attached as Ex. C19 to Tersigni Cert.) ("Use of a hazard statement alone without incorporation of dose to assess potential risk for human health effects is not consistent with generally accepted methods used by toxicologists . . . ."); Expert Report of Kelly Scribner Tuttle, Ph.D., C.I.H. ("Tuttle Rep.") at 7, Feb. 25, 2019 (attached as Ex. C26 to Tersigni Cert.) ("Since all substances can be toxic, evaluation of exposure conditions . . . and dose levels . . . to assess safety is vital for correctly estimating risk.").)

77 (Crowley Dep. 129:7-9.) *See also* Toxicology Reference Manual at 636 ("Even water, if consumed in large quantities, can be toxic.").

(excluding expert testimony that prisoner contracted cancer because he inhaled hazardous radioactive particles where the expert "ha[d] not determine[d] the dose" of radiation to which the inmate had been exposed); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107-08 (8th Cir. 1996) (concluding that trial court should have excluded expert testimony that defendant's emissions caused plaintiffs' injuries because the testimony was "not based on any knowledge about what amounts of . . . formaldehyde involve an appreciable risk of harm to human beings who breathe them"); *Burgad v. Jack L. Marcus, Inc.*, 345 F. Supp. 2d 1036, 1042 (D.N.D. 2004) (a "mere statement" that a certain chemical "has the capacity to cause injury" or that the chemical was present in the product purchased by the consumer was insufficient to establish causation; the effects of exposure to toxic substances "will always be dependent upon the dose, the duration of exposure, the method and manner of exposure, personal traits and habits, and the presence of other chemicals, toxic or otherwise"); *Nat'l Bank of Commerce*, 22 F. Supp. 2d at 967 (finding there was no "reliable scientific proof of causation" because "at no point do plaintiff's experts identify a dosage level of AFM that is known to cause laryngeal cancer in humans").

Plaintiffs' experts' heavy metal opinions must be excluded here because not a single one of plaintiffs' experts was able to identify the supposed threshold for exposure to various heavy metals sufficient to cause ovarian cancer – or even

inflammation.[78] Nor was any expert able to quantify, even in rough terms, the amount of heavy metals to which genital talc users were purportedly exposed,[79] let alone the amount of heavy metals that would reach a woman's ovary through perineal talc use.[80] In other words, none of plaintiffs' experts has even attempted to show that users of the Products would be exposed to heavy metals above any identified threshold known to cause inflammation or ovarian cancer.

Some of plaintiffs' experts claimed – many for the first time at their depositions – that ***any*** exposure to heavy metals, no matter how trivial, is capable

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[78] (*See, e.g.*, Zelikoff Dep. 282:10-24 ("Q. What are the exposure levels of these metals necessary to have biologic plausibility of ovarian cancer? A. As far as biological plausibility of these metals, these metals are – unless there are particular standards for a particular metal, nothing is really established for what it would take for nickel to cause ovarian cancer. However, the ability of these metals to produce inflammation are very, very low levels. And if they produce inflammation, then they have the potential to go on to produce cancer. And many of these metals do.").)

[79] (*See, e.g.*, Carson Dep. 175:6-11, 176:5-10 (agreeing that he did not know the amounts of heavy metals in the Products and that he did not assess a woman's exposure to heavy metals through use of talcum powder); Plunkett Dep. 263:24-264:1 ("No, I have not done a – a calculation of a potential dose with perineal application for any of the heavy metals."); Clarke-Pearson Dep. 292:6-10 ("Q. How, if at all, did you factor the dose fragrances and heavy – or trace heavy metals into your analysis of the potential relationship between those compounds and ovarian cancer? A. I didn't factor in."); Plunkett Dep. 263:12-264:3 (admitting that she had done no analysis to determine the dose of chromium a woman would be exposed to "with perineal application").)

[80] (*See, e.g.*, Carson Dep. 169:17-23 ("Q. Do you have any idea how much of these metals, if any, reaches a woman's ovaries each time they use talc? A. I can't tell you how much, but I can tell you that some does.").)

of causing ovarian cancer.[81]

Courts across the country have rejected this so-called "any exposure" approach to causation as unscientific and unreliable under *Daubert*. *See, e.g.*, *Anderson v. Ford Motor Co.*, 950 F. Supp. 2d 1217, 1224 (D. Utah 2013) (concluding that the "every exposure" theory is "not reliable enough evidence for the [c]ourt to allow it in under the standards of *Daubert* and Rule 702" because it "is based on [plaintiff's experts'] lack of information sufficient to show the level of exposure which does not create a risk of mesothelioma"); *Pluck v. BP Oil Pipeline Co.*, 640 F.3d 671, 679-80 (6th Cir. 2011) ("[I]t is well-settled that the mere existence of a toxin in the environment is insufficient to establish causation without proof that the level of exposure could cause the plaintiff's symptoms."); *In re W.R. Grace & Co.*, 355 B.R. 462, 476 (Bankr. D. Del. 2006) ("The use of the no safe level or linear 'no threshold' model for showing unreasonable risk 'flies in the face of the toxicological law of dose-response, that is, that 'the dose makes the poison,' which refers to the general tendency for a greater dose of a toxin to cause greater severity of responses in individuals, as well as greater frequency of

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[81] (*See, e.g.*, Carson Dep. 171:6-21 (asserting that even a single particle of chromium, cobalt or nickel "within the microenvironment of the inflammatory process . . . is contributing to the carcinogenic potential" of talc); Zelikoff Dep. 319:23-321:1, 321:21-322:21 (claiming that, in her "professional opinion," exposure to even one particle of cobalt, chromium or nickel, either inhaled or applied perineally, could cause inflammation in the ovaries).)

response in populations.'") (citation omitted); *Burgad*, 345 F. Supp. 2d at 1042 ("The mere presence of chemicals . . . is not sufficient, by itself, to establish liability or causation in a products liability action.").

Plaintiffs' experts' "any exposure" theory is even more problematic here because it wholly ignores that many of the trace heavy metals allegedly found in talc are also commonly found in the environment, including in food, drinking water or the air; indeed, chromium, cobalt and nickel are all recognized as essential nutrients in the United States. As the Third Circuit has explained, where exposure to a particular substance is common because the substance is a "'constituent element' of our environment," plaintiffs seeking to prove causation must "demonstrate [that] they have been exposed" to the substance "to a greater extent than anyone else, i.e., that their exposure levels exceeded the normal background level." *In re TMI Litig.*, 193 F.3d 613, 644, 659 (3d Cir. 1999) (citations omitted), *amended in nonmaterial part*, 199 F.3d 158 (3d Cir. 2000). Accordingly, expert causation testimony that does not take into account other "common" sources of toxins in the environment is "decidedly unscientific." *Coleman v. Union Carbide Corp.*, No. 2:11-0366, 2013 WL 5461855, at *38-39 (S.D. W. Va. Sept. 30, 2013) (excluding expert testimony as unreliable and unhelpful where expert failed "to demonstrate that the source of the detected [toxic] substances" was the heavy-metal production facility and not one of the other potential sources "common in the

area" for the same contaminants); *see also Allen*, 102 F.3d at 198-99 (excluding experts' opinions that plaintiff's workplace exposure to chemical, rather than other exposures, was the cause of his brain cancer where the experts "discounted" the other exposures and where the information that the experts had about the plaintiff's workplace exposure was "so sadly lacking as to be mere guesswork"). This is because "[a] well-grounded methodology purposed on following the scientific method irrespective of results would not so easily cast aside potential confounders." *Coleman*, 2013 WL 5461855, at *38-39.

Here, as plaintiffs' experts acknowledge, many of the trace metals purportedly present in talc are "naturally in our bodies" and "present in food, drinking water, bottled water, [and] vitamins."[82] And none of plaintiffs' experts has any evidence suggesting that the levels of these heavy metals are higher in perineal talc users as compared to non-users.[83]

In short, plaintiffs' experts' "any exposure" theory is not based on scientific evidence, but rather on their "lack of information" about the level of exposure to

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82 (Carson Dep. 169:24-170:9; *see also, e.g.*, Moore Rep. at 50-68.)

83 (*See, e.g.*, Carson Dep. 170:10-16; Kane Dep. 325:2-9 ("Q. [T]here's no medical or scientific evidence that you would tell this court that the levels of heavy metals in women who use talcum powder in the genital area are higher than women who have never used talcum powder? A. I'm not aware of studies that have been done that have looked at the levels of those heavy metals in ovarian tissue or blood levels.").)

heavy metals that is sufficient to create a genuine risk to human health and whether the amounts of the metals alleged to be in the Products exceeds that level. *Anderson*, 950 F. Supp. 2d at 1224. Accordingly, these opinions are speculative and unreliable under both *Daubert* and Rule 702 and should be excluded.

C. Plaintiffs' Experts Ignore The Valence State Of Chromium And The Bioavailability Of Nickel, Further Rendering Their Opinions Unreliable.

Finally, plaintiffs' experts compound their errors by ignoring the specific chemical forms of the heavy metals supposedly found in talc, further rendering their opinions unreliable.

1. Chromium

Several of plaintiffs' experts' opinions regarding the carcinogenicity of chromium allegedly found in talc are unreliable for the additional reason that they fail to sufficiently consider the valence state of the metal in opining about its toxicity.

As plaintiffs' experts acknowledge, chromium exists in different forms.[84] The most prevalent and stable form of chromium – chromium (III), or trivalent chromium – "is a naturally occurring element found in rocks, animals, plants, soil, and volcanic dust and gases" where it exists in combination with other elements to

[84] (*See, e.g.*, Zelikoff Rep. at 9.)

form various compounds.[85] Humans may ingest chromium through certain foods, and chromium is present in "certain ambient environments."[86] Chromium (III) is considered non-toxic to humans, and IARC and other agencies have not found it to be carcinogenic.[87]

By contrast, chromium (VI) – or hexavalent chromium – rarely occurs naturally.[88] Instead, it is primarily generated and released into the environment during the manufacturing process, a byproduct of rust inhibitors used in cooling towers and chemicals used in the manufacture of metal chromates and by the chromeplating industry.[89] Studies have shown that chromium (VI) is a carcinogen, but few of those studies provide "adequate exposure data for use in risk estimation."[90]

In opining that chromium allegedly found in talcum powder causes ovarian cancer, a number of plaintiffs' experts ignore the differences between trivalent and hexavalent chromium. Indeed, several of plaintiffs' experts assert that chromium

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85 (*Id.*)

86 (Zelikoff Dep. 289:8-13.)

87 (Tuttle Rep. at 37; Moore Rep. at 52-53.)

88 (Tuttle Rep. at 37.)

89 *See* U.S. Envtl. Protection Agency, CAS No. 18540-29-9, *Toxicological Review of Hexavalent Chromium* 47-48 (1998) (attached as Ex. A144 to Tersigni Cert.).

90 *Id.* at 41.

in talcum powder contributes to the product's carcinogenicity without distinguishing between valence states at all. For example:

- Dr. Carson asserts that "[t]he presence of carcinogenic metals such as chromium . . . in commercial talcum powder products, adds to their carcinogenic potency."[91] His report nowhere differentiates between chromium (III) and chromium (VI). At his deposition, he acknowledged that he did not "know specifically" the valence state of chromium allegedly found in cosmetic talc.[92]

- Dr. Plunkett states that talcum powder contains "toxic compounds" like "chromium" and that chromium is a "*known human carcinogen*."[93] She never acknowledges that different forms of chromium exist.

- Dr. Smith-Bindman asserts that talcum powder contains chromium (VI), but she cites to no published literature, testing data, internal documentation or other evidence supporting that opinion.[94] She does not discuss chromium (III) in her report; nor does she explain that the potential carcinogenicity of chromium can vary depending on its valence state.

And even the experts who do acknowledge that chromium exists in different forms do not offer any opinions as to the form of chromium that is allegedly found in talc. For example, Dr. Krekeler asserts that "high levels of chromium" were observed in certain talc mines, but admits that no testing was conducted to determine the valence state of the chromium.[95] Similarly, Dr. Cook submits that the talc ores "contained high levels of heavy metals including . . . chromium,

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91 (Carson Rep. at 7.)

92 (Carson Dep. 180:17-181:10.)

93 (Plunkett Rep. ¶¶ 29, 36; *see also id.* ¶¶ 67, 101.)

94 (Smith-Bindman Rep. at 16.)

95 (Krekeler Rep. at 36.)

[a] known carcinogen[].”[96] But Dr. Cook did not undertake any testing to determine the “ratio of trivalent Cr(III) versus hexavalent Cr(VI).”[97] Nor do plaintiffs’ experts point to any evidence suggesting that chromium (VI) is more likely to be found in talc than chromium (III). This is not surprising. After all, as Dr. Moore explained, “if chromium is present in talc products, it is most likely in the form of chromium (III) present in rock.”[98]

The only one of plaintiffs’ experts to assert that the Products contain chromium (VI) is Dr. Zelikoff,[99] who attempts to support this position by pointing to a 1968 paper in which “22 cosmetic talcum products purchased off the shelf were analyzed for fibrous content, selected metals and quartz.”[100] In that analysis, the author notes that “[q]ualitative tests showed some of the chromium in the talcum products to be in the hexavalent state.”[101] But there is no indication that

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96 (Am. Cook Rep. at 42.)

97 (*Id.* at 32.)

98 (Moore Rep. at 54.)

99 As noted above, Dr. Smith-Bindman asserts that chromium (VI) is present in talc but cites no supportive evidence and does not acknowledge chromium (III) or the relevance of the differing valence states to carcinogenicity, suggesting that she merely (incorrectly) assumed that the chromium found in talc ore is of the hexavalent variety.

100 (Zelikoff Rep. at 10 (citing Cralley et al., *Fibrous and Mineral Content of Cosmetic Talcum Products*, 29(4) Am Ind Hyg Assoc J. 350 (1968) (“Cralley 1968”) (attached as Ex. A22 to Tersigni Cert.)).)

101 Cralley 1968 at 352.

any of the tested products included JJCI's talcum powder, and in any event, the study concluded that, in most of the products tested, the levels of "cobalt, nickel, chromium, and manganese were generally of a low magnitude and within a narrow range."[102] Accordingly, the study at issue does not support Dr. Zelikoff's opinion that chromium (or any other heavy metal) allegedly found in the Products could cause ovarian cancer.

2. Nickel

Several of plaintiffs' experts also ignore scientific studies indicating that the carcinogenicity of nickel compounds is not determined by the presence of nickel alone, but rather by the degree to which nickel ions are biologically available.

Nickel is a naturally-occurring element found in the earth's crust.[103] A wide range of nickel-containing compounds exists, including some compounds that are soluble and some that are insoluble.[104] Based on animal studies and studies of nickel workers, some nickel compounds have been classified as carcinogenic.[105] These studies have shown that different nickel compounds are associated with different types of tumors. For example, intratracheal instillation (the introduction

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102 *Id.* at 353.

103 Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., Toxicological Profile for Nickel, at 2 (2005) ("ATSDR Nickel Profile") (attached as Ex. A5 to Tersigni Cert.).

104 *See id.* at 2, 15.

105 *Id.* at 7.

of a substance directly into the trachea) of insoluble nickel compounds has been associated with increases in lung tumors.[106] By contrast, a study by NTP using a soluble nickel compound – nickel sulfate hexahydrate – observed no evidence of carcinogenic activity.[107] Given these differences, investigators have proposed that, when assessing the effects of nickel exposure, "it is important to consider what form of nickel a person is exposed to and its bioavailability."[108] For example, in a 2011 study focusing on inhalation, the authors concluded that the bioavailability of nickel ions from different compounds was dependent on each compound's respiratory toxicity, how fast the body was able to clear the compound from the

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106 *See* IARC 2012 Monograph at 192; Int'l Agency for Research on Cancer, World Health Org., 49 *Monographs on the Evaluation of Carcinogenic Risks to Humans: Chromium, Nickel and Welding* 325-326 (1990) (attached as Ex. A71 to Tersigni Cert.); Nat'l Toxicology Program, U.S. Dep't of Health & Human Servs., No. 451, *Toxicology and Carcinogenesis of Nickel Oxide (CAS No. 1313-99) in F344/N Rats and B6C3F1 Mice (Inhalation Studies)* (1996) (attached as Ex. A101 to Tersigni Cert.); Nat'l Toxicology Program, U.S. Dep't of Health & Human Servs., No. 453, *Toxicology and Carcinogenesis of Nickel Subsulfide (CAS No. 12035-72-2) in F344/N Rats and B6C3F1 Mice (Inhalation Studies)* (1996) (attached as Ex. A102 to Tersigni Cert.).

107 *See* Nat'l Toxicology Program, U.S. Dep't of Health & Human Servs., No. 454, *Toxicology and Carcinogenesis Studies of Nickel Sulfate Hexahydrate (CAS No. 10101-97-0) in F344 Rats and B6C3F1 Mice (Inhalation Studies)* (1996) (attached as Ex. A103 to Tersigni Cert.).

108 ATSDR Nickel Profile at 255.

lung, how readily cells absorbed the compound and how readily the compound dissolved into nickel ions.[109]

A number of plaintiffs' experts fail to take the bioavailability of nickel into consideration in rendering their opinions. For example, Dr. Zelikoff opines that "[i]n experimental animals, nickel compounds induce tumors at virtually all sites of application."[110] But as noted above, a two-year inhalation study of rats using nickel sulfate hexahydrate found no evidence of tumors. Likewise, IARC notes that in a two-year, multiple-dose study, oral nickel sulfate hexahydrate did not result in carcinogenesis.[111] These studies show that, in order to draw conclusions regarding the carcinogenicity of nickel in this case, it is important to know the specific form of nickel purportedly found in the Products. For this reason, too, plaintiffs' experts' opinions that nickel contributes to talc's supposed carcinogenicity lack a scientific basis and must be excluded.

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109 *See* Goodman et al., *The nickel ion bioavailability model of the carcinogenic potential of nickel-containing substances in the lung*, 41(2) Crit Rev Toxicol. 142 (2011) (attached as Ex. A48 to Tersigni Cert.).

110 (Zelikoff Rep. at 9 (citations omitted).)

111 IARC 2012 Monograph at 190.

II. DR. CROWLEY'S OPINION THAT THE FRAGRANCES USED IN JJCI'S TALCUM POWDER CONTRIBUTE TO THE PRODUCTS' CARCINOGENICITY LACKS FOUNDATION.

Several of plaintiffs' experts also assert that the fragrances added to the Products contribute to their alleged propensity to cause ovarian cancer. But plaintiffs' primary expert on this topic – Dr. Michael Crowley – consistently misunderstood or misapplied the sources he relied upon to draw his conclusions. And none of plaintiffs' experts is able to point to any scientific literature suggesting a link between exposure to the fragrance substances in the Products and ovarian cancer. In addition, plaintiffs have zero evidence that the dose of the fragrance components, which together account for less than one percent of the overall product, is capable of contributing to the supposed carcinogenicity of talc.

A. Dr. Crowley Lacks "Good Grounds" For His Opinions.

Plaintiffs primarily offer the testimony of Michael Crowley in support of their claim that the fragrances added to the Products contribute to the alleged propensity of these products to cause ovarian cancer. The Court should exclude Dr. Crowley's opinions because he lacks "good grounds" for his conclusions.

Rule 702 requires "expert testimony to be reliably based upon scientific methods." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002), *aff'd*, 68 F. App'x 356 (3d Cir. 2003). In other words, an "expert's opinions must be based on the methods and procedures of science" – i.e.,

"the expert must have 'good grounds' for his or her belief." *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 656 (D.N.J. 2008) (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994)). When an expert takes a step that "completely changes a reliable methodology" or "misapplies [his] methodology," his testimony becomes unreliable and therefore is inadmissible. *In re Paoli*, 35 F.3d at 745; *see also Patrick v. FirstEnergy Generation Corp.*, Nos. 08-1025, 08-1030, 2014 WL 992805, at *2 (W.D. Pa. Mar. 13, 2014) ("[E]xperts are not permitted to engage in a 'haphazard, intuitive inquiry' . . . .") (citation omitted). Likewise, when an expert's conclusions do not "reliably flow from the facts known to the expert and the methodology used," those conclusions must be excluded from trial. *Magistrini*, 180 F. Supp. 2d at 595, 603-08 (citation omitted) (excluding expert whose application of his methodology was unreliable); *see also, e.g.*, *Allgood v. Gen. Motors Corp.*, No. 102CV1077DFHTAB, 2006 WL 2669337, at *29 (S.D. Ind. Sept. 18, 2006) (expert's "misapplication of his own source reveals a methodological flaw critical to his opinion").

Here, Dr. Crowley's opinions lack "good grounds" because they do not "reliably flow from the facts known" to him. Dr. Crowley claims that the ingredients in the fragrances used in Johnson's Baby Powder and Shower to

Shower are "not in compliance with governmental and industry standards."[112] To arrive at this opinion, Dr. Crowley searched materials available in the "public domain" to perform a "regulatory review" of the fragrances in the Products.[113] But many of Dr. Crowley's conclusions are inconsistent with – or contrary to – the information set forth in the sources he cites. For example:

- Dr. Crowley asserts that "Myroxylon Pereirae (Balsam Peru) Oil, present in Baby Powder, is prohibited by the International Fragrance Association (IFRA) for use as a fragrance ingredient and on the EU Annex ii of chemicals prohibited from cosmetics in Europe."[114] But the ingredient that is prohibited by IFRA is peru balsam ***crude***.[115] Peru balsam extracts and distillates – the fragrance ingredient added to Johnson's Baby Powder – are permitted for use in specified quantities. *Id.* At his deposition, Dr. Crowley explained that he confused the two ingredients because they had "the same exact [identification] number."[116] He also offered "to update [his] report" in view of the fact that "the prohibited material" was not the ingredient being used in Johnson's Baby Powder.[117]

- Dr. Crowley asserts that four fragrance ingredients – styrene, coumarin, eugenol and D-limonene – are "potential carcinogens" based on IARC's Group 3 classification.[118] But IARC's Group 3 classification means that a particular substance "is ***not classifiable as to its carcinogenicity in***

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112 (Crowley Rep. at 11.)

113 (*Id.* at 18; Crowley Dep. 110:23-111:15, 360:7-10.)

114 (Crowley Rep. at 11; *see also id.* at 19, 64.)

115 *See* Index of IFRA Standards – 48th Amendment at 9 (attached as Ex. A69 to Tersigni Cert.).

116 (Crowley Dep. 171:23-172:3.)

117 (*Id.* 172:24-173:3.)

118 (*See* Crowley Rep. at 64.)

humans."[119] In other words, for substances that fall into Group 3, there is inadequate evidence that the substance causes cancer in humans – and, to the contrary, there may be "strong evidence that the mechanism of carcinogenicity in experimental animals ***does not*** operate in humans."[120]

- Dr. Crowley claims that benzophenone was "removed from use in foods by FDA . . . due to histiocytic sarcoma observed in ovaries and uterus, higher incidences of kidney tumors and leukemia in animal studies . . . , and in vivo estrogenic activity."[121] But the 2006 NTP study that Dr. Crowley cites in support of this statement did not conclude that benzophenone can cause ovarian cancer; rather, the study's authors concluded that the histiocytic sarcomas they observed "were highly invasive" and affected "[m]ultiple organs."[122] As the FDA noted in discussing this study, histiocytic sarcomas are "rarely reported in humans" and "were found only at dose levels that induced toxicity" in rodents – no increase in tumor incidence was reported at the lowest test dose. Food Additive Regulations; Synthetic Flavoring Agents and Adjuvants, 83 Fed. Reg. 50,490, 50,495 (Oct. 9, 2018). Moreover, the FDA did not decide to remove benzophenone due to any purported concern about human health effects. To the contrary, the FDA concluded that "benzophenone is ***unlikely*** to induce tumors in humans at current use levels as a synthetic flavoring substance and adjuvant in food." *Id.* at 50,495 (emphasis added).

- Dr. Crowley claims that p-cresol is "possibly carcinogenic," pointing to a 1990 report published by the EPA.[123] In that report, the EPA grouped p-cresol as a Classification C carcinogen – a "possible human carcinogen" –

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119 Int'l Agency for Research on Cancer, World Health Org., *IARC Monograph on the Evaluation of Carcinogenic Risks to Humans: Preamble* 23 (2006) (attached as Ex. A73 to Tersigni Cert.).

120 (*Id.* at 64-65.)

121 (Crowley Rep. at 48 (citations omitted); *see also id.* at 65.)

122 Rhodes et al., *Carcinogenesis studies of benzophenone in rats and mice*, 45(5) Food Chem Toxicol. 843, 848-49 (2007) (attached as Ex. A121 to Tersigni Cert.).

123 (Crowley Rep. at 12.)

based on "increased incidence of skin papillomas in mice."[124] In a more recent review, however, the Agency for Toxic Substances and Disease Registry concluded that, based on EPA's updated criteria for carcinogenicity, p-cresol "falls in the category of chemicals for which there is 'inadequate information to assess carcinogenic potential.'"[125]

- Dr. Crowley states that "Musk ketone is suspected of being a carcinogen, and has been classified as a Category 3 carcinogen by the Scientific Committee on Health and Environmental Risks (SCHER) in Europe."[126] SCHER classified musk ketone as a Category 3 carcinogen – i.e., a substance with limited evidence of carcinogenic effect – based on data related to musk xylene because there was no test data for musk ketone itself.[127] The SCHER panel determined that the classification of musk xylene was "a borderline case since an increase in liver tumours in the highly sensitive B6C3F1 mouse is considered of little relevance for human hazard assessment."[128] Notably, the European Union's Institute for Health and Consumer Protection recognized that musk ketone is commonly used in fragrances and determined there was "no need for risk reduction measures" to reduce exposures below current levels.[129]

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124 U.S. Envtl. Protection Agency, *Integrated Risk Information System, 4-Methylphenol; CASN 106-44-5* 4 (1993), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0302_summary.pdf (attached as Ex. A145 to Tersigni Cert.).

125 Agency for Toxic Substances & Disease Registry, U.S. Dep't of Health & Human Servs., Toxicological Profile for Cresols, at 12 (2008) (attached as Ex. A4 to Tersigni Cert.).

126 (Crowley Rep. at 12; *see also id.* at 48.)

127 European Commission Health & Consumer Protection Directorate-General, Sci. Committee on Health & Envt'l Risks (SCHER), *Opinion on Classification of Musk Ketone* 3 (Jan. 2006) (attached as Ex. A34 to Tersigni Cert.).

128 *Id.*

129 *See* European Chemicals Bureau, CAS No: 81-14-1, EINECS No. 201-328-9, *4'-Tert-Butyl-2',6'-Dimethyl-3',5'-Dinitroacetophenone (Musk Ketone) Summary Risk Assessment Report* 27 (2005) (attached as Ex. A33 to Tersigni Cert.).

As these examples make plain, Dr. Crowley engaged in a "haphazard" inquiry to arrive at conclusions that are unsupported by the very data on which he claims to rely. For this reason alone, the Court should exclude his opinions under *Daubert*.

B. Dr. Crowley's Opinions Are Also Unreliable Because There Is No Scientific Evidence Linking Fragrance Exposure To Ovarian Cancer.

As set forth above, courts have made clear that expert opinions are unreliable when there is no scientific literature "supporting a correlation between the suggested causative agent and the type of cancer experienced by the plaintiff." *Burleson*, 393 F.3d at 586; *see also Joiner*, 522 U.S. at 145-46 (district court properly excluded expert opinion that plaintiff's exposure to PCBs contributed to his cancer where the studies underlying the expert's opinion "did not suggest a link between the increase in lung cancer deaths and the exposure to PCB's"); *Nat'l Bank of Commerce*, 22 F. Supp. 2d at 983 (excluding expert testimony on causation where experts could not point to any "scientific studies or medical literature that show[ed] any correlation between exposure to [the purported carcinogen] and laryngeal cancer").

These same principles compel exclusion of Dr. Crowley's fragrance opinions. Dr. Crowley has been offered to support plaintiffs' theory that the fragrances added to JJCI's talcum powder "contribute to the inflammatory

properties, toxicity, and potential carcinogenicity of the products."[130] But as Dr. Crowley repeatedly made clear during his deposition, there are ***no*** studies linking ***any*** of the fragrances used in JJCI's talcum powder to ovarian cancer in humans:

> Q. Are you aware of any publication that links the fragrance chemicals in baby powder and Shower to Shower to ovarian cancer?
>
> A. I don't believe I found a source that made that association.[131]

Plaintiffs' other experts – including plaintiffs' toxicologist (Dr. Zelikoff), regulatory expert (Dr. Plunkett), gynecological oncologist (Dr. Clarke-Pearson) and epidemiologist (Dr. Smith-Bindman) – are in accord: not a single one was able to identify anything in the medical literature connecting the fragrances used in JJCI's talcum powder to inflammation in the ovaries or ovarian cancer.[132]

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130 (Crowley Rep. at 11.)

131 (Crowley Dep. 114:9-15; *see also id.* 199:16-19 ("I am not aware of an epidemiological study substantiating the causation of ovarian cancer from the so-called fragrance chemicals."); *id.* 234:5-20 (confirming that none of the fragrances listed in Table 7 of his report had "been studied for ovarian cancer in humans").) At his deposition, Dr. Crowley repeatedly testified that he lacked knowledge about the effect of fragrance ingredients on human ovaries because it is "unethical" to do "those kind of studies" in humans. (*See, e.g.*, *id.* 222:4-7; *id.* 282:9-12.) But animal studies have identified several agents (not present in the fragrances at issue here) that exhibit "clear or some evidence of carcinogenicity" in the ovaries of animal models. *See* Nat'l Toxicology Program, Organ Sites with Neoplasia Guided Search Health, https://manticore.niehs.nih.gov/cebssearch/support/view/CEBS_Organ-Sites-Neoplasia-Guided-Search-Help.pdf (last updated July 21, 2017) (attached as Ex. A99 to Tersigni Cert.).

132 (*See* Zelikoff Dep. 313:21-314:3 (conceding that none of the chemicals used in fragrances has been reported in the medical literature to induce inflammation in *(cont'd)*

Unable to point to any human studies linking ovarian cancer with fragrances, Dr. Crowley resorts to cell cultures, primarily pointing to studies using Chinese hamster ovary cells as evidence of an animal model that supports an increased risk of ovarian cancer.[133]

Courts routinely "caution against direct extrapolation from cellular . . . studies to humans." *In re Zoloft (Sertraline Hydrochloride) Prods. Liab. Litig.*, 26 F. Supp. 3d 466, 477 (E.D. Pa. 2014). This is because in vitro studies "necessarily remove the cells from the dynamic metabolic context in which the human body actually processes chemical compounds." *In re Accutane Prods. Liab.*, 511 F. Supp. 2d 1288, 1294-95 (M.D. Fla. 2007). Accordingly, "[a] positive animal study merely suggests that there might be a need to study the agent in humans"; it does

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the ovaries); Plunkett Dep. 275:13-25 (no scientific evidence indicating that the fragrances were capable of causing ovarian cancer); Clarke-Pearson Dep. 289:12-290:8 (stating that he was not aware of any scientific literature indicating that the fragrances in JJCI's talcum powder could cause ovarian cancer or inflammation); Dep. of Rebecca Smith-Bindman, M.D. Vol. II 320:21-25, Feb. 8, 2019 (attached as Ex. B42 to Tersigni Cert.) ("Q. There have been no fragrance chemicals, to your knowledge, that have been found in a study to be associated with ovarian cancer, correct? A. I – I know of no – no such exploration.") (objection omitted).)

[133] (*See* Crowley Dep. 217:12-218:5 ("we have animal studies that show toxicity issues with cells in animal models, like Chinese hamster ovary cell models"); *id.* 117:10-12 (asserting that benzyl alcohol was found to be "cytogenic in Chinese hamster ovary cells" in a National Toxicology Program study conducted in 1989); *id.* 221:20-222:2 ("Q. Is d-Limonene a genotoxic material? A. I don't believe it's been classified as that, but cytotoxicity against Chinese hamster ovary cells indicates that it could be against ovaries, at least in this animal model.").)

not "render an admissible opinion" that a substance is toxic in humans. *Wade-Greaux*, 874 F. Supp. at 1469; *see also, e.g., In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 429-35 (S.D.N.Y. 2005) (finding that cell studies of rats were not "a reliable basis for extrapolating to the liver of a living human").

Here, although Dr. Crowley agreed that "it's possible that an ingredient can cause or contribute to the development of cancer or a cancer in an animal but not in humans,"[134] he never explains the basis for his extrapolations from the animal studies he cites – none of which is supported by human data. This is not surprising; after all, none of the studies, including the in vitro studies using hamster ovary cells, shows an increase in rates of ***ovarian cancer***. *See, e.g., Perry v. Novartis Pharm. Corp.*, 564 F. Supp. 2d 452, 466 (E.D. Pa. 2008) (expert conclusion that exposure to drug could cause non-Hodgkin lymphoma not reliable where studies showed that animals developed lymphoma or non-lymphoma tumors but not specifically non-Hodgkin lymphoma); *cf. In re Accutane*, 511 F. Supp. 2d at 1295 (cell studies that used cancer cells could not be reliably extrapolated to normal intestinal cells). Moreover, cell-line studies like those using hamster ovary cells "necessarily remove the cells from the dynamic metabolic context in which the human body actually processes chemical compounds." *In re Accutane*, 511 F. Supp. 2d at 1294-95. The female reproductive and immune systems, by contrast,

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134 (Crowley Dep. 212:22-213:2.)

involve a number of different types of cells and include natural repair mechanisms for foreign substances. Thus, while in vitro studies like the ones relied upon by Dr. Crowley may "suggest[] that there might be a need to study the agent in humans," they cannot support an opinion that any fragrance ingredient is toxic in humans. *Wade-Greaux*, 874 F. Supp. at 1469. This is particularly true given that – as Dr. Crowley admits – a number of factors affect how a body responds to fragrances, including the "route of administration" and "the kinetics of how [the fragrances are] metabolized, distributed, and eliminated."[135]

Notably, the relevant literature makes clear that Chinese hamster ovary cells are commonly used in mutagenicity assays because they "exhibit a routine cloning efficiency higher than 80% in a reasonably well-defined medium."[136] While data obtained from Chinese hamster ovary cell assays may "indicate a likelihood or potential of the test chemical to be a mutagen or carcinogen for humans . . . a direct correlation between mutagenicity in the CHO/HGPRT assay and in animals or humans is not fully established."[137] Therefore, data from Chinese hamster ovary cells should not be "a basis for classifying chemicals either as animal or human

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135 (Crowley Dep. 214:5-22.)

136 Hsie et al., *The Use of Chinese Hamster Ovary Cells to Quantify Specific Locus Mutation and to Determine Mutagenicity of Chemicals. A Report of the Gene-Tox Program*, 86(2) Mutat Res. 193, 196 (1981) (attached as Ex. A66 to Tersigni Cert.).

137 *Id.* at 205.

mutagens/carcinogens or as nonhazardous" or to "establish acceptable exposure levels."[138] Moreover, the cells "in no way represent the target tissue of the chemical being tested."[139] Thus, Dr. Crowley's suggestion that the results from assays using hamster ovary cells indicate that human ovary cells are apt to react similarly lacks foundation and therefore cannot support his opinions either.

C. Dr. Crowley's Failure To Analyze Dosage Further Renders His Opinions Inadmissible.

Dr. Crowley's fragrance opinions are inadmissible for another, independent reason: his failure to identify a dose-response threshold, i.e., the level of exposure to fragrance ingredients that would be necessary to cause harm.

At his deposition, Dr. Crowley acknowledged the "central tenet" of toxicology noted above that dose is critical,[140] explaining that "most materials could be hazardous if too much is consumed or if the exposure is too great."[141] Nevertheless, Dr. Crowley did not perform a dose-response assessment in this case for any of the fragrances in the Products.[142]

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138 *Id.*

139 (Moore Rep. at 89.)

140 *See* Toxicology Reference Manual at 636.

141 (Crowley Dep. 129:7-9.)

142 (*Id.* 124:3-13.)

Specifically, Dr. Crowley does not know the exposure levels at which the fragrances can allegedly cause ovarian cancer.[143] He also does not know the amount of any particular fragrance ingredient in the Products.[144] As a result, Dr. Crowley does not know the amount of any fragrance ingredient to which a woman is exposed through talc use.[145] Accordingly, Dr. Crowley's fragrance opinions must be excluded for all the same reasons explained in connection with plaintiffs' experts' heavy metal opinions in Section I.B, above.

Dr. Crowley's attempts to defend his opinion despite this fundamental shortcoming all lack merit.

First, in lieu of identifying true levels of exposure ostensibly associated with ovarian cancer, Dr. Crowley attempts to rely on regulatory thresholds identified for some of the fragrances at issue. For example, Dr. Crowley states that, "[o]f the

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143 (*Id.* 309:12-20.)

144 (*See, e.g., id.* 225:14-19 (does not know the concentration of d-Limonene in the Products); *id.* 232:23-233:4 (does not know the concentration of benzaldehyde in the Products); *id.* 252:19-253:3 (does not know the concentration of styrene in the Products).)

145 (*Id.* 201:7-202:6; *see also id.* 225:21-226:3 (does not know what dose of d-Limonene a woman would be exposed to through talc use); *id.* 233:5-13 (does not know the amount of benzaldehyde to which a woman using talcum powder would be exposed); *id.* 253:7-14 (does not know "the amount of exposure or the duration of exposure" to styrene from talcum powder use); *id.* 207:16-22 (admitting that he has done no testing or analysis to quantify the difference between the dose applied to the perineal region and the dose that would reach the ovaries).)

141 fragrance chemicals in the product, 23 fragrances have a Category 5 Restriction" – meaning that IFRA has set exposure limits to those fragrances.[146]

But regulatory thresholds are set according to policy and precautionary principles; they are no substitute for scientific evidence establishing dangerous levels of exposure. *See, e.g.*, *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1249 (11th Cir. 2005) ("[T]he procedures commonly used in 'risk assessment' for the purpose of establishing public health guidelines that represent 'acceptable' exposure levels for large populations are often . . . of marginal relevance to estimating 'causation' . . . .") (quoting David L. Eaton, *Scientific Judgment and Toxic Torts–A Primer in Toxicology for Judges and Lawyers*, 12 J.L. & Pol'y 5, 34 (2003)). And in any event, as already noted, Dr. Crowley has no evidence that use of the Products would result in exposure that exceeds these thresholds. To the contrary, he expressly disclaimed such knowledge.[147] Accordingly, regulatory thresholds at best serve to highlight Dr. Crowley's failure to prove dose, rather than justify it.

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146 (Crowley Rep. at 39.)

147 (Crowley Dep. 209:10-210:2; *see also, e.g.*, *id.* 327:2-331:2 (stating that although there are "a bunch of" fragrance chemicals that have exposure restrictions, he was unable to "make a judgment as to whether [the fragrance] present in baby powder exceeds" the regulatory threshold or not).)

Second, Dr. Crowley blames his failure to conduct a dose-response assessment or determine whether the amount of fragrance chemicals in talc exceeded safe limits on the fact that he was not provided with "information to know how much of each fragrance chemical was in the composition."[148] This argument also fails.

As a threshold matter, Dr. Crowley's protest that he did not perform an essential step in proving causation because he lacked sufficient data once again only confirms, rather than negates, the unreliability of his opinions. As another court explained in excluding plaintiffs' causation experts, "[t]he failure to address the issue of dosage in a scientific manner is just one more reason to conclude that plaintiffs' experts did not reach their conclusions on the basis of the scientific method." *Perry*, 564 F. Supp. 2d at 472 (excluding experts that made "no attempt to demonstrate sufficient dosage, but instead simply ignore the question of dosage entirely making only vague and unquantifiable statements like '[plaintiff] was exposed to a substantial amount of pimecrolimus cream for a prolonged period of time'") (citation omitted); *see also, e.g.*, *Wade-Greaux*, 874 F. Supp. at 1481 ("Because the methodologies of plaintiff's expert witnesses do not even consider human therapeutic doses, I conclude that those methodologies are so patently

[148] (*Id.* 124:3-13; *see also id.* 200:24-201:5 ("Q. You have not been able to do a dose response analysis. Correct? A. Again, I couldn't do it because I didn't have the information from J&J, I suppose, to enable doing that.") (objection omitted).)

unreliable and unlikely to lead to accurate results that they would be unhelpful to a trier of fact."); *Nat'l Bank of Commerce v. Dow Chem. Co.*, 965 F. Supp. 1490, 1502 (E.D. Ark. 1996) ("At a minimum, we think that there must be evidence from which the fact finder can conclude that the plaintiff was exposed to levels of that agent that are known to cause the kind of harm that the plaintiff claims to have suffered."), *aff'd*, 133 F.3d 1132 (8th Cir. 1998) (per curiam).

In any event, the basic premise of Dr. Crowley's complaint – that he did not have the data he needed – is wrong. A number of documents that were produced to plaintiffs – including documents that Dr. Crowley cites in his report – list the maximum concentration of fragrance ingredients in the Products. For example, the formulation documentation shows that Johnson's Baby Powder contained a maximum of 0.22 percent fragrance ingredients,[149] and other documents produced in discovery revealed the constituent ingredients of the fragrance.[150] While Dr. Crowley complained that the documents he saw did not include units,[151] units are not necessary to understand exposure levels. Even without units, it is easy to discern that each ingredient is necessarily less than 0.22% of ingredients in each exposure to talc (since 0.22% is the total amount of all fragrance ingredients

149 (*See* JNJTALC000891091.)

150 (Attorneys' Eyes Only Exs. 1-3.)

151 (Crowley Dep. 124:8-13.)

combined). And the numbers provided for each fragrance ingredient, even without units, allows the reader to roughly estimate what portion of that 0.22% is made up of each ingredient because the numbers are relative – the maximum amount of the first ingredient is listed as 25.0, for example, while maximum amounts of other ingredients are 10.0, 5.0, 1.0 or 0.1. Minimum amounts are also provided. Thus, for a given volume of product, it would be possible to estimate the maximum possible exposure to each fragrance ingredient by assuming the maximum amount of that ingredient and the minimum amount of each of the other ingredients and then calculating the maximum relative portion of the ingredient at issue.[152] That is what defendants' toxicology expert Dr. Kelly Tuttle did, a simple calculation that led her to conclude that "none of the fragrant chemicals [are] present at a concentration where the normal use of the products at issue would result in an adverse health effect."[153] Accordingly, Dr. Crowley's complaints are unfounded and would not rescue his opinion even if they were well placed.

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[152] To the extent Dr. Crowley or plaintiffs really had difficulty analyzing these documents, they could have sought clarification in discovery.

[153] (Tuttle Rep. at 67.) Dr. Crowley's failure to even attempt to approximate any woman's exposure to fragrance chemicals is especially problematic in light of the mega-doses used in the animal studies upon which he relies. (Crowley Dep. 272:15-273:5.) *See Wade-Greaux*, 874 F. Supp. at 1454 ("High dosage animal studies cannot be relied upon to determine whether a substance is teratogenic in humans in therapeutic doses."); *Perry*, 564 F. Supp. 2d at 472 (excluding causation opinions where plaintiffs' experts "fail[ed] to address the disparity in the dosages [plaintiff] received and the dosages in the animal studies on which they rely").

Third, Dr. Crowley also attempted to excuse his failure to conduct a dose-response assessment by suggesting for the first time at his deposition that "some of the[] fragrance chemicals are genotoxic."[154] According to Dr. Crowley, a dose-response assessment is unnecessary in such circumstances because genotoxins only "need one molecule for there to be an increased risk."[155] As an initial matter, even if it were established that a particular fragrance were genotoxic,[156] that fact would not be sufficient to classify the material as carcinogenic.[157] In any event, Dr. Crowley is simply wrong in asserting (without support) that dose is irrelevant to genotoxicity.[158] For example, as explained by Dr. Tuttle, studies of the

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154 (Crowley Dep. 124:14-16.)

155 (*Id.* 124:16-20; *see also id.* 125:20-23 (explaining that genotoxic materials "don't have a threshold" because "[o]ne molecule is enough to cause an increased risk").)

156 In his report, Dr. Crowley asserted that "[s]everal chemicals in the fragrance mixture used by J&J" had demonstrated "genotoxicity" in cell and animal studies but also acknowledged that the studies "were not definitive that the same effects would be observed in humans." (Crowley Rep. at 21.) Moreover, Dr. Crowley's report only identifies some ingredients as potentially genotoxic; thus, his genotoxicity excuse for ignoring dose does not apply to the vast majority of ingredients he addresses.

157 *See, e.g.*, Nat'l Toxicology Program, U.S. Dep't of Health & Human Servs., No. 389, *Toxicology and Carcinogenesis Studies of Sodium Azide (CAS No. 26628-22-8) in F344/N Rats (Gavage Studies)* (1991) (attached as Ex. A100 to Tersigni Cert.) (noting that sodium azide is genotoxic in assays but does not cause cancer).

158 *See, e.g.*, Toxicology Reference Manual at 636 (noting that whether a substance can cause harm is, in all circumstances, "a question of dose") (citation omitted).

genotoxicity of ethanol have reported effects at some levels of exposure but not others, suggesting that dose is relevant to whether ethanol has genotoxic effects.[159] Thus, the notion that Dr. Crowley should be excused from considering dose for any ingredient that someone has suggested might be genotoxic is unscientific and unreliable.

For all of these reasons, Dr. Crowley's opinions about any purported relationship between the fragrances used in JJCI's talcum powder and ovarian cancer should be excluded.

D. The Opinions Of Plaintiffs' Experts Parroting Dr. Crowley Should Also Be Excluded.

A number of plaintiffs' experts simply adopt Dr. Crowley's conclusion that the fragrances added to the Products "may contribute" to the "potential carcinogenicity" of those products.[160]

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[159] (Tuttle Rep. § 6.3, at 12 (citing Registry of Toxic Effects of Chemical Substances (RTECS) database and Toxicology Data Network (TOXNET)) (collecting genotoxicity studies that evaluate dose response).)

[160] (Zelikoff Rep. at 12; *see also* Clarke-Pearson Rep. at 6 (citing Crowley report for proposition that the "fragrance chemicals in talcum powder" contain "carcinogens"); Kane Rep. at 5 ("For purposes of my opinions, I have reviewed and relied upon Dr. Crowley's report regarding the fragrance chemical constituents in Johnson & Johnson talcum powder products . . . . ") (citation omitted); Plunkett Rep. ¶ 35 (citing Dr. Crowley's report for the proposition that "over 70%" of the fragrances "have been linked with some level or irritant hazard"); Singh Rep. at 60 (stating that the "fragrance ingredients . . . are known or suspected carcinogens" and citing Dr. Crowley's report); Smith-Bindman Rep. at 16 ("I reviewed the expert report from Dr. Crowley that concludes that some of these chemicals may *(cont'd)*

These experts should be precluded from offering any opinions that simply parrot those of Dr. Crowley. As one court explained in excluding such opinions under Federal Rule of Evidence 703, "[a] scientist, however well credentialed he may be, is not permitted to be the mouthpiece of a scientist in a different specialty." *Dura Auto. Sys. of Ind., Inc. v. CTS Corp.*, 285 F.3d 609, 614 (7th Cir. 2002). This is because allowing an expert to offer an opinion in an area where he or she lacked expertise "would not be responsible science." *Id.*; *see also TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732 (10th Cir. 1993) (expert opinions improper under Rule 703 where expert has "professed no expertise" with respect to the issue at hand and had no "familiarity with the methods or reasoning" used by the expert whose opinions he was adopting). This principle applies with special force here because, as set forth in the preceding sections, Dr. Crowley's opinions lack good grounds and are unreliable for a variety of reasons. For this reason, too, the Court should exclude all of plaintiffs' experts' opinions related to fragrances in the Products.

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contribute to the inflammatory response, toxicity, and potential carcinogenicity of Johnson & Johnson's talcum powder products. I concur with his opinion."); Smith Rep. at 19 (similar); Carson Rep. at 6 (similar); Moorman Rep. at 35 (similar); Levy Rep. at 16 (similar); Wolf Rep. at 10 (similar).)

III. PLAINTIFFS' EXPERTS' OPINIONS THAT THE PRODUCTS CONTAIN CARCINOGENIC FIBROUS TALC SHOULD BE EXCLUDED BECAUSE THEY ARE BASED ON AN ERRONEOUS DEFINITION.

Finally, several of plaintiffs' experts contend that the Products contain fibrous talc and that this renders the Products carcinogenic. All of these opinions suffer from the same central flaw: they confuse the "fibrous talc" that Longo and Rigler claim to have found (i.e., any talc particle with "a 5:1 aspect ratio or greater, at least 0.5 µm in length and [having] substantially parallel sides") with the ***different*** "fibrous talc" addressed by IARC. When referring to fibrous talc, IARC means talc that contains asbestiform fibers or talc that grew in an asbestiform habit (respectively referred to as "talc with asbestiform fibers" and "asbestiform talc" in this brief). Importantly, that is ***not*** what Longo and Rigler (or the experts who parrot their findings) are referring to as fibrous talc.

An expert opinion, even if reliable, should be excluded if "there is simply too great an analytical gap between the data and the opinion proffered." *Joiner*, 522 U.S. at 146; *see also, e.g.*, *In re TMI Litig.*, 193 F.3d at 683 (excluding several experts for lack of fit and noting that expert opinion must be excluded when it does not "reliably flow from the facts known by the expert and the methodology used") (citation omitted). In keeping with this principle, an expert cannot depend on the carcinogenic effects of one substance to support a conclusion about a related substance without showing a basis for treating the two substances similarly. *See*

Magistrini, 180 F. Supp. 2d at 603-04 (excluding expert who relied on analogous chemicals because "[i]t is not contested that certain chemicals are structurally and functionally similar to one another . . . where the former is a known carcinogen and the latter is known to pose no carcinogenic risk whatsoever"); *see also, e.g., Soldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 472 (W.D. Pa. 2003) ("[G]iven the documented diversity of this chemical group, any reliance on general rules or principles purportedly associated with [these chemicals] as a group would be particularly inappropriate.").

Here, a number of plaintiffs' experts opine that the elongated talc that Longo and Rigler claim to have identified in the Products can cause cancer by relying on literature about an ***entirely different substance*** – i.e., talc with asbestiform fibers or asbestiform talc. For example:

- Dr. McTiernan states that "[t]he conclusions reached in [IARC's] 100c monograph about asbestos apply to fibrous talc."[161]
- Dr. Smith contends that "[a]ccording to IARC, all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite[)] and talc containing asbestiform fibers (fibrous talc) are carcinogenic."[162]
- Dr. Wolf opines that "[t]he conclusions reached by [IARC] about asbestos and its carcinogenic risks apply to [chrysotile, crocidolite, amosite,

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161 (McTiernan Rep. at 57 (citing IARC 2012 Monograph).)

162 (Smith Rep. at 18.)

tremolite, actinolite, and anthophyllite] wherever they are found, and *includes talc containing asbestiform fibres* (fibrous talc)."[163]

- Dr. Plunkett cites IARC for the proposition that "talc containing asbestiform fibers was classified in 1986 as a known human carcinogen."[164]

- Dr. Zelikoff states that "[i]n its fibrous form, talc has been classified as a Group I, known carcinogen."[165]

- Dr. Cook contends that "[f]ibrous talc fulfills the requirements for inclusion with asbestiform minerals which are known human carcinogens."[166]

- Dr. Singh states that "IARC has also concluded that talc including asbestiform fibers grown in an asbestiform habit – commonly termed 'fibrous talc' is 'carcinogenic to humans.'"[167]

- Dr. Smith-Bindman claims that "asbestiform talc particles . . . have a similarity in structure to asbestos fibers (and . . . IARC concludes [they] are carcinogenic)" and also states that IARC's findings of carcinogenicity "applied to . . . asbestiform talc (fibrous talc)."[168]

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163 (Wolf Rep. at 9 (citing IARC 2012 Monograph).)

164 (Plunkett Rep. at 21 (citing Int'l Agency for Research on Cancer, World Health Org., *Monographs on the evaluations of carcinogenic risks to humans. Overall evaluations of carcinogenicity: An updating of IARC Monographs Volumes 1 to 42 (Suppl. 7)* (1987) ("IARC 1987 Monograph"), IARC 2010 Monograph, IARC 2012 Monograph).)

165 (Zelikoff Rep. at 4 (citing IARC 1987 Monograph, IARC 2010 Monograph, IARC 2012 Monograph).)

166 (Am. Cook Rep. at 2.)

167 (Singh Rep. at 16 (citing IARC 2010 Monograph).)

168 (Smith-Bindman Rep. at 5, 15 (emphasis omitted).) Other experts mention the supposed carcinogenic potential of fibrous talc in an even more perfunctory manner. These opinions should be excluded as well. (*See, e.g.*, Carson Rep. at 5; Clarke-Pearson Rep. at 5; Kane Rep. at 9; Kessler Rep. at 19; Moorman Rep. at 35, 39; Siemiatycki Rep. at 65-66.)

But it is crystal clear that IARC – which does not even use the term "fibrous talc" – addresses something else. Specifically, rather than addressing the elongated talc particles of the sort Longo and Rigler claim to have identified, IARC classifies "***talc containing asbestiform fibres***" as carcinogenic. As IARC explains, "'[t]alc containing asbestiform fibres' is a term that has been used inconsistently in the literature."[169] Most properly, "it applies to talc containing asbestiform fibres of talc or talc intergrown on a nanoscale with other minerals, usually anthophyllite" (a form of amphibole with an asbestiform variant that is, in fact, asbestos); but it is also used by some to mean "talc products that contain asbestos" generally, and by others to mean any "talc products that contain elongated mineral fragments that are not asbestiform."[170]

The same monograph makes clear, however, that talc products that merely contain elongated mineral fragments, that are not "intergrown" with asbestos – i.e., the talc that Drs. Longo and Rigler call fibrous talc – are not carcinogenic.[171]

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169 (IARC 2012 Monograph at 230.)

170 (*Id.*)

171 (*See id.* (noting that grouping "elongated mineral fragments that are not asbestiform" with talc containing asbestiform fibers is "erroneous"); *id.* at 219 ("[T]he conclusions reached in this *Monograph* about asbestos and its carcinogenic risk apply to ***these six types [i.e., chrysotile, crocidolite, amosite, tremolite, actinolite, or anthophyllite]*** wherever they are found, and that includes talc containing asbestiform fibres.") (emphasis added).) Dr. Wolf and Dr. Singh appear to agree with this definition. (*See* Wolf Rep. at 9; Singh Rep. at 16; *see also* Wolf *(cont'd)*

IARC reached the same conclusion two years earlier in its monograph, confirming that talc without asbestiform fibers has not been shown to be carcinogenic, explaining that ***talc "may . . . be elongated without being asbestiform"*** and therefore without being dangerous.[172] Thus, by conflating talc that contains or is intergrown with true asbestos or grows in an asbestiform habit with mere elongated talc particles, plaintiffs' experts fail to heed IARC's express warning that "differences in the use of the . . . term must be considered when evaluating the literature on talc."[173]

Several plaintiffs' experts, in particular Drs. Krekeler and Cook, also attempt to bolster their opinions with citations to defendants' internal documents, which they claim show that the Products, or raw talc, or mines from which talc was sourced, contained trace amounts of "fibers" or "fibrous talc."[174] But none of these experts provides any basis to assume that any of these fibers were asbestos, or even asbestiform. Indeed, Dr. Cook admits that many of them did not grow in a fibrous

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Dep. 168:8-9 ("Fibrous talc is asbestos").) But their opinions nevertheless depend on conflating it with the long, thin non-asbestos particles purportedly identified by Drs. Longo and Rigler.

172 (IARC 2010 Monograph at 277 (emphasis added).)

173 (IARC 2012 Monograph at 230.)

174 Reliance on these documents to show the contents of talc is further unreliable for all of the reasons laid out in defendants' memorandum in support of their motion to exclude plaintiffs' asbestos-related opinions. (*See* Defs.' Mem. in Supp. of Mot. to Exclude Pls.' Experts' Asbestos-Related Ops. at 94-103.)

habit at all. Instead, their shape could be "attributed to . . . modification during the milling process."[175]

For all of these reasons, the Court should exclude plaintiffs' experts' opinions regarding fibrous talc.

CONCLUSION

For the foregoing reasons, defendants respectfully request that the Court exclude the opinions proffered by plaintiffs' experts regarding alleged heavy metals, fragrances or fibrous talc that are set forth on the following pages of plaintiffs' experts' reports:

- Pages 5-8 of the Expert Report of Arch Carson;
- Pages 6 and 9 of the Expert Report of Daniel Clarke-Pearson;
- Pages 2, 4, 9-10, 20-26 and 40 of the Expert Report of Robert Cook;
- The entirety of the Expert Report of Michael Crowley;
- Pages 5, 29 and 36 of the Expert Report of Sarah Kane;
- Pages 19 and 21 of the Expert Report of David Kessler;
- Pages 23-30 and 45 of the Expert Report of Mark Krekeler;
- Pages 15-17 of the Expert Report of Shawn Levy;
- Page 15 of the Expert Report of William Longo and Mark Rigler;
- Pages 8-9 and 56-57 of the Expert Report of Anne McTiernan;

[175] (Am. Cook Rep. at 28.)

- Pages 17-21, 23-24, 25-26, 46, 53, 55, 67-69 and 77-78 of the Expert Report of Patricia Moorman;
- Pages 17-21, 23-26, 46, 53, 55, 67-69 and 77-78 of the Expert Report of Laura Plunkett;
- Pages 65-66 of the Expert Report of Jack Siemiatycki;
- Pages 15-16 and 60 of the Expert Report of Sonal Singh;
- Pages 18-19 and 21-22 of the Expert Report of Ellen Blair Smith;
- Pages 5, 14-16 and 40 of the Expert Report of Rebecca Smith-Bindman;
- Pages 9-10 and 15-16 of the Expert Report of Judith Wolf; and
- Pages 4, 8-12 and 27 of the Expert Report of Judith Zelikoff.

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Respectfully submitted,

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